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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/900,425	07/06/2001	Hongjiang Wu	ISPH-0522	7138

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EXAMINER
MCGARRY, SEAN

ART UNIT	PAPER NUMBER
1635	19

DATE MAILED: 06/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/900,425	WU ET AL.	
	Examin r	Art Unit	
	Sean R McGarry	1635	

-- The MAILING DATE of this communication appears on th c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *16 April 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) *5-18 and 20-52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4 and 19* is/are rejected.

7)☒ Claim(s) *3* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The claimed invention (claims 1-4 and 19) is awarded a priority date of, 07/06/01, the filing date of the instant application. The parent applications were reviewed and no support for SEQ ID NO: 2 or enabled support for the claimed invention in general could be found in 09/479,783, 08/870,608, or 08/659,440. An application for a patent for an invention which is also disclosed in a prior application (the parent or provisional application); the disclosure of the invention in the parent application and in the second application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ 2d 1077 (Fed. Cir. 1994). If applicant believes that the prior applications provide enabling support for the claimed invention, applicant is invited to point specifically to that support. (Repeated from previous Official Action)

Claims 1, 2 and 4 and 19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

It is noted that Claim 4 was not included in the rejection of record set forth in the Official Action mailed 12/16/02, however, it is clear from the rejection and the Official Action as a whole that claim 4 was clearly intended to be included in the rejection. For

example, claim 19, which depends from claim 4, was rejected. Also it is clear that, although applicant asserts otherwise, the claimed invention of claim 19 and 4 were clearly addressed in the rejection of record since both claims are broadly drawn to the inclusion of a generic "human RNase III". If applicant disagrees with this assertion, applicant should provide evidence or arguments that the RNase III claimed in original claims 1-3 differs from that human RNase III in claims 4 and 19.

The specification discloses SEQ ID NO:2 which corresponds to a human RNase III. SEQ ID NO: 2 meets the written description provisions of 35 USC 112, first paragraph. However, the claims are directed to encompass mutated sequences, allelic variants, splice variants, sequences that have a recited degree of homology, and so forth. None of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NO:2, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written

description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it.

University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In *re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

Therefore, only SEQ ID NO: 2 but not the full breadth of the claim (or none of the sequences encompassed by the claim) meets the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant as evidenced by Wu et al [J. of Biological Chemistry Vol. 275, No. 47:36957-36965, 2000] at page 36957, column 2 last paragraph, for example. Applicant is reminded that Vas-Cath makes clear that the

written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Applicant's arguments filed 4/16/03 have been fully considered but they are not persuasive.

Applicant asserts that the instant specification provides several examples of species of human RNase III polypeptides at page 8 and in Example 6. It is noted that the polypeptides disclosed at page 8 and in Example 6 are polypeptides (20mers of a protein SEQ ID NO: 3 that is 1374 amino acids in length) made for antibody production and were not shown to have RNase III properties. Page 32 and Examples 9 and 10 shows that a fusion protein that includes the c-terminal-most 466 amino acids of SEQ ID NO: 2 can cleave double stranded RNA *in vitro.* Applicant also asserts that the specification provides a comparison of various other RNase III polypeptides from other species and asserts that the above indicates that applicant was in possession of several species at the time of filing. It is noted that all that appears to be described in the application, as far as human RNase III polypeptides that cleave double stranded RNA, is SEQ ID NO: 2 and a fusion protein that contains the 466 c-terminal-most amino acids of SEQ ID NO: 3. Applicant argues Example 14 of the "Revised Written Description Guidelines Training Materials" in support of the scope of what is claimed. It is noted that although the examiner does not agree that SEQ ID NOS: 35 and 36 (20mers made to make antibodies) provide any support whatsoever for RNase III polypeptides that cleave double stranded RNA, the specification does provide guidance for a structure, the 466

c-terminal-most amino acids of SEQ ID NO: 2, that provides for the function of double stranded RNA cleavage. Claims 2 and 3 provide for a sequence [that provides for the function of double stranded RNA cleavage] via the 90% limitation (for claim 2) and further, since the specification provides for a method of screening for the activity of such sequences, it is clear that one could make such sequences from the description of SEQ ID NO: 2, however, claim 3 does not recite a correlated function as detailed in Example 14, for example. Claim 3, is limited to containing SEQ ID NO: 2 and is therefore allowable. Claims 1, 4 and 19 fail to provide for structure while claim 2 fails to provide a function. Therefore the claims fail to provide a structure that would be correlated with a function. Claims 1, 4 and 19 provide for structures unrelated to SEQ ID NO: 2 and more specifically other than that structure, the 466-cterminal-most amino acids of SEQ ID NO: 2 that provides for the function of double stranded RNA cleavage and claim 2 fails to provide for a function that would correlate with a recited structure (e.g. 90% identity but with any function that may or may not have been correlated in the art or instant specification with such a structure, for example).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-4 and 19 **were** rejected under 35 U.S.C. 102(a) as being anticipated by Wu et al. [The Journal of Biological chemistry Vol. 275(47): 39657-36965, 2000].

Wu et al disclose an RNase III protein with SEQ ID NO: 2 (See Figure 1, for example). Wu et al further disclose the administration of antisense oligonucleotides to Hela cells (which contain RNase III, for example). It is assumed, without evidence to the contrary, that the antisense oligonucleotides were administered with a pharmaceutically acceptable carrier since these oligonucleotides were administered to live cell, for example.

This rejection has been withdrawn in view of the Declaration of Hongjiang Wu under 37 CFR 1.131 on 4/16/03. Although the Wu et al. reference indicates that Hongjiang Wu and Hong Xu contributed equally to the results of the work published in the Wu et al reference, Hongjiang Wu avers that the work was done under the direction of Hongjiang Wu or other representatives of the assignee.

Claim 3 is objected to as being dependent upon rejected base claims, but would be allowable if rewritten in independent form including all of the limitations of the base claims and any intervening claims.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Wu et al., The Journal of Biological Chemistry,Vol. 273(5):2532-2542, discloses the isolation of activity of a human RNase III in a cell extract but do not disclose an isolated polypeptide *per se*.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean R McGarry whose telephone number is (703)305-7028. The examiner can normally be reached on M-Th (6:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SEAN McGARRY
PRIMARY EXAMINER

SRM
June 23, 2003

SEAN McGARRY
PRIMARY EXAMINER